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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,913	02/06/2001	Hyman M. Schipper	S&B-C048	3680

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EXAMINER

WINSTON, RANDALL O

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/776,913	Schipper et al.
	Examiner Randall Winston	Art Unit 1654
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b>		
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>		
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.138 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
1) <input type="checkbox"/> Responsive to communication(s) filed on _____.		
2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
<b>Disposition of Claims</b>		
4) <input checked="" type="checkbox"/> Claim(s) <u>2-14</u> is/are pending in the application.		
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>2-14</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
<b>Application Papers</b>		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
<b>Attachment(s)</b>		
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____		

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## **DETAILED ACTION**

### ***Response to Amendment***

The request for reconsideration filed on April 38, 2003 has been entered.

Claims 2-14 are pending.

### ***Claim Objections***

Claims 11-14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. (please see 102 explanation below of what applicants claim)

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out distinctly claim the subject matter which applicant regards as the inventions.

Claims 9 and 10 recite the limitation "the concentration of HO-1 mRNA." There is insufficient antecedent basis for the limitation in the claim.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Perrella et al. (US 5,888,982).

Applicant claims a commercial package comprising means for determining the concentration of heme oxygenase-1 (HO-1) and/or a nucleotide sequence encoding HO-1, in bodily fluid or non-neural tissue obtained from a patient.

Perrella et al. anticipate the claimed invention because Perrella et al. teach an assay that includes an HO-1 specific antibody linked to a detectable label and an HO-1 promoter sequence linked to a reporter gene, each of which is capable of providing a means for determining the

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concentration of heme oxygenase-1 (HO-1) and/or a nucleotide sequence encoding HO-1 in non-neuronal tissue (i.e. vascular tissue) obtained from a patient (see, e.g. column 2, lines 8-14, column 2, lines 20-22, column 2 lines 32-34, column 7 lines 41-44 and column 8 lines 4-9). The reference HO-reagents (e.g., HO-1 specific antibody and/or HO-1 sequence) would necessarily and inherently be contained within a commercial package (e.g., within a vial or other commercial containers/packages).

Please note that it is legally well established that printed matter-e.g., providing instruction to a known product, to show its intended use does not lend patentable distinction to the product, *per se*-i.e., a well known compound, packaged and labeled to show its new use, is not patentable (see, e.g., *In re Haller*, 73 USPQ 403). Therefore, the printed instructions showing intended use fail to lend patentable distinction to the claimed invention.

Therefore, the reference anticipates the instant above claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 103(a) as being unpatentable over Perrella et al.

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The primary reference is relied upon for the reasons discussed above. Although not expressly taught, the adjustment of these and other conventional working conditions (e.g., placing well known agents within a commercial package such as a vail or a kit), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER